

Application No. 10/081,478  
Amdt. Dated August 23, 2007  
Reply to Office Action of March 23, 2007

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### REMARKS/ARGUMENTS

#### 1. Remarks of the Amendment

Claims 21-36 have been canceled without prejudice.

New Claims 37-43 have been added to more specifically define Applicant's claimed invention. Antecedent basis of the amendment can be found in the claims and the Specification as filed.

More specifically, in Claim 37 antecedent basis of continuous grooves can be found in Figs. 9 and 10; and antecedent basis of the first and second sizes of the grooves being different can be found on page 11, lines 16-22 and on page 12, lines 15-20 of the Specification as filed.

Applicants respectfully submit no new matter has been introduced by the amendments.

#### 2. Response to the Double Patenting Rejection

Claim 21 stands rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 2, 18, and 22 of U.S. Patent No. 6,419,491 and Claims 1, 8 and 9 of U.S. Patent No. 6,454,569, and provisionally rejected nonstatutory obviousness-type double patenting as being unpatentable over Claims 1 of Application No. 09/784,284.

Applicants submit herein three Terminal Disclaimers, together with the requested fees under 37CFR 1.20(d).

Accordingly, Applicants respectfully request withdrawal of the double patenting rejections.

#### 3. Entitlement of Earlier Priority of the Instant Application

Applicants submit that new independent Claim 37, amended further from Claim 21, entitles the early priority of the parent application 08/146,790 filed November 2, 1993.

More specifically, Applicants provide herein the analysis of each application in the

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train of earlier-filed applications to show the disclosure that independent Claim 37 is entitled to the benefit of the filing dates of the parent application 08/146,790. The analysis is specifically made with regard to the comments made by the Examiner in the Office Action, and the further amendment made from Claim 21.

(1). "planar substrate"

(a) In the earliest parent application Serial No. 08/146,790, planar substrate is described on page 17, second paragraph. The specific description is recited below:

"substrate can be provided in the form of flat, planar members having one or more of these microgeometric texturized design and configurations formed on their planar surfaces."

(b) Application Serial No. 08/390,805 was a continuation of the application Serial No. 08/146,790 with the same specification.

(c) Application Serial No. 08/639,712 were filed as a continuation of the application Serial No. 08/390,805 with the same specification.

(d) In application Serial No. 08/996,244, the same description recited above can be found on page 19, third paragraph.

(e) In application Serial No. 09/500,038, the experimental results of the bone tissue grown on a planar substrate are shown in Figs. 20-21 and 22-23. It is important to point out that the application Serial No. 09/500,038 described the same tissue growth experimental results on the grooved substrate of the parent applications. The cell growth results were illustrated by bar graft in Figs. 13-21 of the four earlier applications, while in Serial No. 09/500,038 the results were illustrated by the scanning electron micrographs of the substrate surface after the grown bone tissue was separated.

It is specifically pointed out that the description of the results of the bone and soft tissue cell growth on 2-micron and 4-micron grooved surfaces on page 22, illustrated by Fig. 20-21 of Serial No. 09/500,038 were the same as those described on page 9 of Serial No. 08/146,790. Further, the description of the results of the tissue growth on 12-micron grooved surface on page 23 of application Serial No. 09/500,038 were the same as those described on page 10, second paragraph of application Serial No. 08/146,790. Moreover, as described on page 23, second paragraph of application Serial No. 09/500,038, "the textured substrates were further studied to determine the preferable

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substrates and their structure for control of cell growth." Then, the oriented cell growth and attachment on the experimental surfaces illustrated by Figs. 20-21 were further described. (Recitations of some of these descriptions can also be found below.)

(2). "a plurality of continuous grooves"

(a) In application Serial No. 08/146,790, a plurality of continuous grooves were disclosed by Figs. 5A and 5B.

(b)-(c) Continuation application Serial Nos. 08/390,805 and 08/146,790 had the same disclosures.

(d) In application Serial No. 08/996,244, a plurality of continuous grooves were disclosed by Figs. 5A and 5B.

(e) In application Serial No. 09/500,038, a plurality of continuous grooves were disclosed by Figs. 1 and 2.

(3). "promoting soft tissue cell growth" "promoting bone cell growth" and "said first size and said second size are different".

(a) In application Serial No. 08/146,790, these elements were described throughout the application Serial No. 08/146,790 in various manners. The particular relevant descriptions are recited below:

"The microgrooved textured zones with various sizes of the grooves promote different types of tissue growth. ....(2) microgrooved textured zones having the grooves size in a specific size range to promote the bone cell growth over soft fibrous tissue growth; (3) microgrooved textured zones having the grooves size less approximate than a specific size range to stimulate fibrous tissue growth over the bone tissue growth". (see page 8, second paragraph)

"These different microgeometric texturized design surfaces are proved to:

a. promote the rate and orient the direction of bone growth and discourage the growth of soft tissue to achieve secure fixation of the

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implant surfaces to bone tissue;

b. promote the rate and orient the direction of the growth of soft tissue while discouraging the growth of bone tissue to achieve soft tissue integration with the implant surfaces;" (see page 8, fourth paragraph, and page 9, first paragraph).

"the 2- $\mu$ m indentation or groove surface would provide a 32.8% decrease in bone/soft tissue growth, providing a significant advantage in soft tissue cell growth" (see page 9, fourth paragraph).

"The surface with the highest ratio of bone to soft tissue cell growth is the 12- $\mu$ m indentation or groove substrate. The basis for the ratio is the fact that this surface inhibits soft tissue colony growth by 53.1% relative to controls" (see page 10, second paragraph).

It is noted that the terms of soft tissue growth, soft tissue cell growth, and soft tissue colony growth were used interchangeably in the early applications. Similarly, the terms of bone growth, bone tissue growth, and bone cell growth were also used interchangeably.

(b)-(c) Continuation application Serial Nos. 08/390,805 and 08/146,790 had the same disclosures.

(d) In application Serial No. 08/996,244, the above recited descriptions can be found on page 8, first to fourth paragraphs, page 11, last paragraph, and page 12, second paragraph.

(e) In application Serial No. 09/500,038, similar descriptions as recited above can be found on page 20, second to fourth paragraphs, page 22, lines 8-10, and page 23, first paragraph.

Based on the above analysis, Applicants have clearly shown that independent Claim 37 is entitled to the benefit of the filing date of the parent application 08/146,790, i.e., November 2, 1993.

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#### 4. Response to the Rejections of Claim 21, 28 and 29 Based Upon 35 USC §102(b)

Claims 21, 28 and 29 were rejected under 35 U.S.C. §102(b) as being anticipated by Frey (U.S. Patent No. 3,848,273). These claims have been replaced by new Claim 37 and this rejection is respectfully traversed by the amendment.

For there to be anticipation under 35 U.S.C. §102, "each and every element" of the claimed invention must be found either expressly or inherently described in a single prior art reference. *Verdegaal Bros vs. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and references cited therein. See also *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1581, 230 USPQ 81, 84 (Fed. Cir. 1986) ("Absence from the reference of any claimed element negates anticipation."); *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). As pointed out by the court, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. *ATD Corp V. Lydall, Inc.*, 159 F.3d 534, 545, 48 USPQ 2d 1321, 1328 (Fed. Cir. 1998). See also *In re Spada*, 911 F.2d 705, 708, 15 USPQ ed 1655, 1657 (Fed. Cir. 1990).

As positively recited in the independent Claim 37, Applicants' claimed substrate comprises a plurality of continuous grooves.

Applicants submit that the claimed subject matter is not disclosed, taught or suggested by the art of record. More specifically, Frey fails to teach Applicants' claimed substrate having microtextured surface of a plurality of continuous grooves.

On the contrary, Frey expressly teach that the surface of shank 3 has a textured zone which is, as indicated in Fig. 1, trough-like discrete unconnect recesses or depressions between teeth of a regular or uniformly formed toothing.

Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §102(b) based on Frey.

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5. Response to the Rejections of Claim 21-23 and 28-32 Based Upon 35 USC §102(e)

Claim 21-23 and 28-32 were rejected under 35 U.S.C. §102(e) as being anticipated by von Recum et al. (U.S. Patent No. 5,011,494). These claims have been replaced by new Claims 37-39, and this rejection is respectfully traversed by the amendment.

Applicants submit that the claimed subject matter is not disclosed, taught or suggested by the art of record. More specifically, von Recum et al. fail to teach Applicants' claimed planar substrate comprising microgeometric textured surfaces, wherein a first of the surfaces comprises a plurality of continuous grooves of a first size having a width and a height of about 2 to about 8 microns for promoting soft tissue cell growth; and a second of the surfaces comprises a plurality of continuous grooves of a second size having a width and a height of about 8 to about 12 microns for promoting bone cell growth; and wherein the first size and the second size are different.

Therefore, the reference fails to anticipate or suggest Applicant's claimed invention.

With regard to Claims 38-39, these claims are dependent upon independent Claim 37. Under the principles of 35 U.S.C. §112, 4<sup>th</sup> paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, Independent Claim 37 is not anticipated by the prior art of record, as such Claims 38-39 are submitted as being allowable over the art of record.

Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §102(b) based on von Recum et al.

6. Response to the Rejections of Claims 22-27 and 30-36 Based Upon 35 USC §103(a)

Claims 22-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nalman et al (U.S. Patent No. 5,607,607), in view of Curtis et al. (U.S. Patent No. 5,833,641). These claims have been replaced by new Claims 37-43 and this rejection is respectfully traversed.

As stated in Section 3 of this response, the claimed invention entitles the

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priority of the parent application 08/146,790, filed November 2, 1993. As such, U.S. Patent No. 5,607,607 (Naiman et al.) is not a proper reference under 35 U.S.C. §103(a). Similarly, U.S. Patent No. 5,833,641 (to Curtis et al.) is not a proper reference either.

Therefore, Applicants maintain that Applicants' claimed invention defined by Claims 37-43 is not obvious in view of the art of record.

Accordingly, Applicants respectfully request withdrawal of rejections under 35 U.S.C. §103(a).

In view of the above, it is respectfully submitted that Claims 37-43, the pending claims, are now in condition for allowance and such action is respectfully requested.

Applicant's Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

8/23/2007

Date of Signature

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